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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,900	05/26/2000	John P. Carulli	032796-019	8399

21839 7590 06/12/2002

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/578,900	Applicant(s) CARULLI ET AL.	
	Examiner J. Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 and 8-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 1-47 are pending in the application.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1, 2, 6 and 7), and election of the species "a protein" is acknowledged. The traversal is on the ground(s) that there is no search burden to search for the different inventions. This is not found persuasive because although the search required for each group may be related, they are not co-extensive. Therefore, because each group requires a different search a burden does exist, and restriction is appropriate.
2. Claims 3-6 and 8-47 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. Furthermore, claims 1, 2, 6 and 7 are generic to a plurality of disclosed patentably distinct Restriction Subgroups of the claimed invention. These subgroups are independent and distinct because each molecule comprising each polymorphic site is structurally and functionally distinct because the chemical structure of the polymorphism differs from one another. For example, the polynucleotide "b200e21-h_Contig4_12.nt" is chemically and structurally from the polynucleotide "b527d12-h_Contig089_1HP.nt".

Applicant is required under 35 U.S.C. 121 to elect a single disclosed restriction subgroup, even though this requirement is traversed. Specifically, applicants must elect either SEQ ID NO. 1 or one polymorphism of Table 4.

In order to be perfectly clear, the following subgroups within the particular Groups are NOT species elections. These are independent and distinct for the reasons given above.

The 26 Restriction Subgroups of the claimed invention are:

(i) SEQ ID NO. 1

(ii)-(xxvi) Table 4: "b200e21-h_Contig4_12.nt" through
"b527d12-h_Contig089_1H.nt"; respectively.

It is pointed out that the polymorphisms listed in Table 4 are not clearly linked to any SEQ ID No. Therefore, it is unclear how to search the claimed nucleic acid polymorphisms. For example, the polymorphism named "b200e21-h_Contig4_12.nt" has the location listed as "27402 (309G)" and comprises an "A/G" base change. It appears as if this polymorphism is located at nucleic acid position 27402. However, this location can be found in at least 4 different SEQ ID Nos. (see SEQ ID No. 7, 8, 9 and 11; each of which comprises more than 29000 nucleotides). Therefore, the polymorphisms of Table 4 must clearly identify which SEQ ID No(s) comprise(s) each polymorphism, in order for a proper search to be performed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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4. A telephone call was made to Mercedes Meyer on April 15, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
June 7, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER